

REMARKS

Applicant respectfully requests reconsideration. Claims 1-23 and 25 were previously pending in this application. By this amendment, Applicant is canceling claims 5 and 9 without prejudice or disclaimer. Claims 1, 8, 10, 11, 14-16, 18-23 and 25 have been amended. As a result, claims 1-4, 6-8, 10-23 and 25 are pending for examination with claims 1 and 15 being independent claims.

Claim 1 has been amended to incorporate the features of claims 5 and 9. Claim 1 also has been amended into steps (a) to (c) to clarify the method. Step (a) has been amended to specify that the method comprises obtaining “a cannabidiol-containing primary extract of the plant material by any one of maceration, percolation or solvent extraction and optionally conducting a further secondary extraction step to obtain a secondary extract”. This language is supported in the specification at page 8, lines 1-34. Step (b) has been amended to specify that the primary or secondary extract obtained is dissolved in a non-polar solvent to form a solution. In addition the features of the non-polar solvent were moved from the end of the claim into step (b) to clarify the claim. Finally, step (c) has been amended to incorporate the feature of previous claim 5, i.e., to specify that the insoluble material is removed by filtration.

Claim 8 has been amended to specify that the primary extract of the plant material is a botanical drug substance.

Claim 10 has been amended to be dependent from claim 8.

Claims 14, 15 and 23 have been amended to specify that the extraction is a solvent extraction. Additional minor amendments to the numbering of the steps were made to claims 15, 16 and 23.

Claims 18-23 and 25 have been amended to be method claims and to be dependent on claim 1.

Applicant has amended the specification to add a heading for "Brief Description of the Drawings".

No new matter has been added.

Objections to the Specification

The Examiner objected to the specification because it lacks a brief description of the drawings. Applicant has amended the specification to provide the appropriate heading for the description of the drawings that existed in the application as filed at page 12, lines 8-36. Accordingly, withdrawal of this objection is respectfully requested.

Rejections Under 35 U.S.C. § 103

1. The Examiner rejected claims 1-13, 18-23 and 25 under 35 U.S.C. § 103(a) as being unpatentable over Webster et al. (US 6,403,126 B1) alone or in view of Adams (US 2,304,669) and further in view of Schmidt et al. (US 2003/0017216 A1).

Webster describes a method of extracting cannabinoids from industrial hemp by the use of a solvent extraction followed by a fractionation procedure. In the described process, a crude extract of the industrial hemp is first prepared by solvent extraction. This crude extract is then passed through an HPLC column, so that the Δ^9 -THC is retained by the column.

The Examiner has stated that column 5, lines 3-25 of Webster discloses a “desire to obtain purified cannabinoid which is free of Δ^0 -THC [*sic*, Δ^9 -THC].” Office Action at page 4. This is not correct – the eluent from the HPLC column used by Webster is a “whole hemp extract” containing no Δ^9 -THC, which is retained by the column. This is not equivalent to a “purified cannabinoid” or, more particularly, to the claimed substantially pure CBD, since it will contain other components of hemp. The Δ^9 -THC held on the column may be eluted and the fractions collected, pooled and concentrated.

In effect, Webster describes two methods. The first is directed to the production of a “whole hemp extract” which lacks Δ^9 -THC and the second to the production of substantially pure cannabinoids. Both methods make use of a general extraction to remove *all* useful components from hemp, followed by a fractionation step to produce extracts with selected components.

The only disclosure in Webster of the production of *pure* cannabinoids, and in particular of pure CBD, involves the use of this fractionating step (see Example II). Even then, the conditions for the isolation of CBD are not given.

The use of fractionation is therefore an *essential* feature of the method of Webster if it is desired to purify a specific cannabinoid. By contrast, the method of the current invention provides a simplified method of obtaining substantially pure CBD without the use of fractionating systems such as HPLC. Such systems are difficult and expensive to implement on an industrial scale. Webster does not contain any teaching that would enable the skilled person to produce substantially pure cannabidiol *without* the use of a fractionating system. For example, Example 1 describes the use of solvent extraction steps and filtration to produce an extract, which is a whole hemp extract. There is no disclosure relating to the chemical composition of this extract, and in particular no evidence whatsoever that it equates to anything of substantial purity, let alone CBD. Furthermore, the disclosure at column 5, line 3, indicates that such extracts are intended to be subjected to a fractionation step following any solvent extraction and/or filtration steps. Such a step is described in general terms in Example II of Webster. It would not have been obvious to a person skilled in the

art from the teaching of Webster that a preparation of CBD of such high purity as described by the current invention could be achieved without the use of a fractionating step, because there simply is not teaching or suggestion of this in Webster.

The Adams patent is cited to indicate that pure crystalline cannabidiol can be obtained from hemp extracts and that the melting point of cannabidiol is 66-67°C. Adams does not provide the elements of the claimed invention that are missing from Webster.

The Examiner attempts to make use of the teaching of Schmidt to bolster the obviousness objection based on Webster, alleging that it would have been obvious for the skilled person to adjust the solvent extraction step of Webster by changing the polarity and hydrophilicity of the solvent (as described by Schmidt, paragraph [0014]). However, as discussed above, the skilled person following the teaching of Webster would expect to have to use a fractionating system to obtain cannabinoids of any significant purity. The teaching of Schmidt reinforces this thinking, since it makes reference to the use of “fractional distillation and column chromatography of the extracts ... to isolate the major components of the Cannabis extracts” (paragraph [0018]).

Thus the combined disclosures of Webster, Schmidt and Adams does not provide the method of the current claimed invention. Moreover, the combination of references would not provide a reasonable expectation of success in obtaining the claimed invention.

Accordingly, withdrawal of this rejection is respectfully requested.

2. The Examiner rejected claims 1-23 and 25 under 35 U.S.C. §103(a) as being unpatentable over Whittle et al. (WO 02/064109 A2) in view of Webster et al. (US 6,403,126 B1) and further in view of Schmidt et al. (US 2003/0017216 A1) and Adams et al. (US 2,304,669).

The Examiner considers that the skilled person would have found it obvious to replace the supercritical CO₂ extraction described by Whittle with the initial hydrocarbon-based extraction of Webster. The Examiner bases the motivation of the skilled person in combining these steps on the teaching of Webster, where the alternative solvents are all given as equivalents in the initial extraction step (col. 3, lines 1-9) that may be used interchangeably. However, as discussed above, the skilled person following the teaching of Webster would consider it necessary to combine such a general extraction step with fractionation in order to obtain pure cannabinoids. Thus, the skilled person seeking to produce purified CBD would have no motivation to replace the supercritical CO₂ extraction of Whittle with the hydrocarbon-based extraction of Webster, even more so since Webster teaches that these are equivalent solvents for the production of general extracts.

The method of Whittle corresponds to one embodiment of step (a) of claim 1 as amended. The skilled person, combining Whittle and Webster, would not consider a further solvent extraction step using a C5-C12 straight chain or branched alkane or carbonate ester of a C1-C12 alcohol (step (b) of claim 1 as amended) to be a suitable improvement upon either method. Instead, the skilled person would be directed towards the use of fractionation as clearly taught by Webster.

Thus, even if the skilled person were somehow motivated to substitute solvents, which Applicant contends is not the case, the skilled person would not have a reasonable expectation of success in using a solvent extraction method because Webster teaches that it is necessary to combine a general extraction step with fractionation in order to obtain pure cannabinoids.

The surprising finding that highly pure preparations of CBD can be achieved by the simple solvent extraction steps of the currently claimed method provides evidence of non-obviousness.

Accordingly, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §§ 102/103

The Examiner rejected claims 18-22 and 25 under 35 U.S.C. § 102(b) or § 103(a) as being anticipated by or obvious over Adams (US 2,304,669).

Claims 18-22 and 25 have been amended to recite method claims that are dependent upon and include the features of claim 1. These claims are novel and non-obvious over the Adams patent in view of their recitation of the features of claim 1.

Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

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Respectfully submitted,

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